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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/650,039  | 08/28/2003  | Ronald J. Pettis     | 11219-060-999                 | 6947             |
| 20583   | 7590        | 08/09/2006           | EXAMINER                      |                  |
| JONES DAY<br>222 EAST 41ST ST<br>NEW YORK, NY 10017 |             |                      | HUMPHREY, LOUISE WANG ZHIYING |                  |
|   |             |                      | ART UNIT                      | PAPER NUMBER     |
|   |             |                      | 1648                          |                  |

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |  |  |
|------------------------------|---|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/650,039      | <b>Applicant(s)</b><br>PETTIS, RONALD J. |  |
|                              | <b>Examiner</b><br>Louise Humphrey, Ph.D. | <b>Art Unit</b><br>1648                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24-35 and 41-91 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 41-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 24-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/17/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

This Non-Final or Final Office Action is in response to the After-Final amendment filed on 17 May 2006. There were two claim 38 and two claim 65, which have been renumbered. Claims 23 and 36-40 have been canceled. Claims 1-22, 24-35, and 41-91 are pending, of which claims 1-21 and 41-91 are withdrawn from consideration and claims 22 and 24-35 are under examination.

### ***Response to Arguments***

#### Objection to Abstract

The objection to the abstract **is withdrawn** in view of Applicant's amendment.

#### Double Patenting

The statutory provisional double patenting rejection of claims 22-35 as being unpatentable over claims 28-41 of copending Application No. 10/487,485 ('485) is maintained but held in abeyance until indication of allowable subject matter.

The nonstatutory provisional double patenting rejection of claims 22-24, 26, and 31 as being unpatentable over claims 2, 4, and 29 of copending Application No. 09/606,909 ('909) will be withdrawn upon Applicants' submission of a compliant terminal disclaimer.

#### Claim Rejections - 35 USC § 102

The rejection of claims 22-28 and 30-35 under 35 U.S.C. §102(b) as being anticipated by Zahn *et al.* (2000, "Zahn") **is withdrawn** in view of the amendment adding the limitation of "alpha-interferon" and the cancellation of claim 23.

The rejection of claims 22-28, 31 and 33-35 under 35 U.S.C. §102(e) as being anticipated by Henry *et al.* (1998, "Henry") **is withdrawn** in view of the amendment adding the limitation of "alpha-interferon" and the cancellation of claim 23.

Claim Rejections - 35 USC § 103

The rejection of claims 22, 36, 38, and 40 under 35 U.S.C. §103(a) as being obvious over Henry *et al.* (1998) in view of Sato *et al.* (1996, "Sato") **is withdrawn** in view of the cancellation of claims 36, 38, and 40.

The rejection of claims 22, 29, 36-38, and 40 under 35 U.S.C. §103(a) as being obvious over Zahn *et al.* (2000) in view of Sato *et al.* (1996) **is withdrawn** in view of the cancellation of claims 36, 38, and 40 and Applicant's statement that Sato *et al.* do not teach administration of  $\alpha$ -interferon itself or genes expressing  $\alpha$ -interferon.

New Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22, 24-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Supersaxo *et al.* (1988, IDS citation No. C31) in view of Zahn *et al.* (2000).

The instant invention is a method of delivering  $\alpha$ -interferon intradermally through one or more microneedles.

Supersaxo *et al.* disclose that intradermal delivery of  $\alpha$ -2a-interferon results in absorption mainly by the lymphatics. Supersaxo *et al.* do not disclose one or more microneedles.

Zahn *et al.* describe a method of short-term intradermal drug delivery (see abstract) through an array of microneedles (page 295, right column, line 3) with an outer height of 0.1 mm (page 298, right column, line 13), which can handle 90° bends (page 295, right column, line 17). The size of the array is at least five by five. Each microneedle is much narrower than a 20-gauge needle. See figure 1. This method increases the flow capacity (abstract), which encompasses enhancing absorption rate and increasing the drug bioavailability, which is experimentally manifested in a decreased  $T_{max}$ , an increased  $C_{max}$ , a decreased  $T_{lag}$ . Zahn *et al.* further disclose that since the shape of a microneedle is defined lithographically, microneedles can be any size. See Introduction, first ¶. Zahn *et al.* further describe the substance to be delivered with this microneedle device is a drug, cell, or cellular based vaccine. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the  $\alpha$ -interferon delivery method of Supersaxo *et al.* by adopting the microneedle array method as taught by Zahn *et al.* The skilled artisan would have been motivated to do so to increase the absorption rate and drug bioavailability, which ultimately improves the effectiveness of the therapeutic material. There would have been a reasonable expectation of success, given that it is already routine in the art to intradermally deliver  $\alpha$ -interferon with regular needles, as taught by Supersaxo *et al.* and that the microneedles are an improvement of stainless steel needles because of its submicro tip radii and the location of the fluid outlet on the side of the needle rather than right at the tip like stainless steel needles, as taught by Zahn

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*et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### **Contact Information**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner

*LuH*  
8/3/06